

**REMARKS**

Claims 1, 3, 4, 8-19, and 21-26 are pending. Claims 1, 3, 4, 8-16, 21-24, and 26 have been rejected. Claims 17-19 and 25 are allowed.

**Claim Rejections - 35 U.S.C. §112**

The Examiner rejected independent Claims 8 and 21 as well as Claims 9-16, 22, and 23 which depend therefrom, respectively, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response to the Examiner's rejection, Applicants have amended independent Claims 8 to call for, *inter alia*, "a sleeve having an outer portion engageable with the female junction element and an inner portion engageable with the male junction element, the sleeve being positionable between the male and female junction elements while the outer portion of the sleeve engages the female junction element and the inner portion of sleeve engages the male junction element." Similarly, Applicants have amended independent Claims 21 to call for, *inter alia*, "positioning the sleeve between the first and second components to provide a separation between the male and female portions while the outer portion of the sleeve engages the female portion and the inner portion of sleeve engages the male portion." It is Applicants belief that this amendment clarifies the subject matter regarded as Applicants invention, specifically, that the sleeve separates the male and female portions when in use. In view of these amendments, Applicants respectfully request removal of the 35 U.S.C. §112 rejection.

**Claim Rejections - 35 U.S.C. §102**

Claims 1, 3, and 4 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,607,560 to Pfaff et al. ("Pfaff '560").

Pfaff '560 discloses joint prostheses 1, as shown in Fig. 1, including shaft 2 and spherical head 3. Spherical head 3 has a conical bore 4 which receives cone 5 of shaft 2 therein. Positioned between and securing cone 5 of shaft 2 to conical bore 4 of spherical head 3 is coupling element 6. By utilizing coupling element 6, the uniform "transfer of force between the cone and the spherical head" is achieved. Pfaff '560, col. 1, lines 61-62.

Applicants respectfully submit that amended independent Claim 1 is not anticipated by Pfaff '560. Specifically, independent Claim 1 calls for the combination of a sleeve and a modular

orthopedic implant including, *inter alia*, a first component with a female junction element and a second component with a male junction element receivable within the female junction element to couple the components together in *direct, self-locking taper relationship*. In contrast to amended independent Claim 1, coupling element 6 of Pfaff '560 is necessary to couple conical bore 4 of head 3 to securing cone 5 of shaft 2. Absent coupling element 6, shaft 2 and head 3 are incapable of being coupled together in *direct, self-locking taper relationship*. Specifically, as shown in Fig. 1, conical bore 4 is substantially oversized with respect to securing cone 5 of shaft 2. This difference in size prevents the components from entering a *direct, self-locking taper relationship*.

Advantageously, the present invention provides for a sleeve which can be inserted between corresponding male and female tapers of an orthopedic component, i.e., self-locking tapers, to temporarily maintain the components in an assembled arrangement. Application Serial No. 10/749,483, [0014]; *see* [0013]. The use of the sleeve between corresponding tapers prevents damage to the components, allows for easy removal and exchange of trial components, and may provide sufficient friction to hold the parts together during trial fitting. *Id.* at [0013]-[0015]. Then, after the trial fitting has concluded, the sleeve can be removed and the male and female tapers of the orthopedic component engaged to taper lock the same together.

For the foregoing reasons, Applicants respectfully submit that amended independent Claim 1, as well as Claims 3 and 4 which depend therefrom, are not anticipated by Pfaff '560.

Claims 1, 3, 4, 8, 10, 14-16, 21, 23, and 26 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,802,866 to Bunz ("Bunz '866").

Bunz '866 discloses prosthesis shaft 2 anchored in ball head 3 by a tapered friction joint formed with a tapered bore. Additionally, positioned within a groove formed in shaft 2 is cushioning element 1. Cushioning element 1 includes indentations 6 matched to the contour of the edge of socket insert 4, allowing the edge of socket insert 4 to enter indentations 6 and provide maximum freedom of movement to shaft 2. Cushioning element 1 may be made of plastic.

Applicants respectfully submit that amended independent Claims 1, 8, and 21 are not anticipated by Bunz '866. Specifically, amended independent Claim 1 calls for, *inter alia*, a male junction element receivable within the female junction element to couple the components together in *direct, self-locking taper relationship* and a sleeve having an outer portion engageable with a female junction element and an inner portion engageable with a male junction element, the

sleeve being positionable between the male and female junction elements while the outer portion of the sleeve engages the female junction element and the inner portion of sleeve engages the male junction element. Similarly, amended independent Claim 8 calls for, *inter alia*, a male portion and the female portion being directly engageable in self-locking taper relationship and a sleeve having an outer portion engageable with a female portion and an inner portion engageable with a male portion, the sleeve being positionable between the male and female portions to provide a separation between the male and female portions while the outer portion of the sleeve engages the female portion and the inner portion of sleeve engages the male portion. Amended independent Claim 21 calls for, *inter alia*, providing a male portion and the female portion being directly engageable in self-locking taper relationship and positioning a sleeve between the first and second components to provide a separation between the male and female portions while the outer portion of the sleeve engages the female portion and the inner portion of sleeve engages the male portion.

In contrast to amended independent Claims 1, 8, and 21, cushioning element 1 of Bunz '866 is not positionable between the male and female portions *while the outer portion of the sleeve engages the female portion and inner portion of sleeve engages the male portion*. In contrast, the tapered friction joint formed by ball head 3 and prosthesis shaft 2 results from the direct engagement of a female portion of ball head 3 with a male portion of prosthesis shaft 2. Bunz fails to provide any indication that the outer portion of cushioning element 1 may be engaged with the female portion of ball head 3 while the inner portion of cushioning element 1 is engaged with the male portion of prosthesis shaft 2. In fact, cushioning element 1 of Bunz '866 is positioned within a groove formed in prosthesis shaft 2 to allow for the male portion of prosthesis shaft 2 to engage the female portion of ball head 3. Therefore, cushioning element 1 would be unable to be received over a female portion of prosthesis shaft 2, i.e., the portion that is *engageable in direct, self-lock taper relationship* with ball head 3, such that the outer portion of cushioning element 1 would engage the female portion of ball head 3, as called for in amended independent Claims 1, 8, and 21.

For at least the foregoing reasons, Applicants respectfully submit that amended independent Claims 1, 8, and 21, as well as Claims 3, 4, 10, 14-16, 23, and 26, which depend therefrom, are not anticipated by Bunz '866.

Claims 8-10, 13, 14, 16, 21, and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,921,500 to Averill et al. ("Averill '500").

Averill '500 discloses femoral stem 12 including post 18 and ceramic femoral hip component 30 having socket 32 with inner seating surface 34. Inner seating surface 34 of socket 32 is tapered at a taper which is steeper than the taper provided along the outer seating surface 26 of post 18. Averill '500, col. 4, lines 30-34. To facilitate the connection between inner seating surface 34 and outer seating surface 26 adapter 40 is provided.

As discussed above, Averill '500 utilizes adapter 40, which is necessary to lock stem 12 and socket 32 together. Thus, the device disclosed in Averill '500 fails to disclose a first component with a male junction element having a tapered male portion and a second component with a female junction element having a tapered bore *corresponding to the male portion, the male portion and female portion being directly engageable in direct self-locking tapered relationship to couple the components together* and a hollow resilient sleeve having an outer portion engageable with the female portion and inner portion engageable with the male portion, as called for in independent Claim 8 and 21. Moreover, if adaptor 40 of Averill '500 was taken to be one of the first component or the second component called for in independent Claims 8 and 21, Averill '500 would then lack a sleeve, as required by amended independent Claims 8 and 21.

Additionally, the Examiner attempts to read the various limitations of amended independent Claims 8 and 21 on different, discrete implant embodiments, each of which is incapable of functioning in combination with the other. Specifically, on page 6 of the Office Action of February 12, 2007, the Examiner indicates:

Averill et al. clearly discloses that the male junction element 18 of the femoral stem and the female junction element 32 of the femoral head are directly engageable in a self-locking taper relationship when the femoral head and the femoral stem are made of metal. When the femoral head is made of ceramic [i.e., is a different embodiment] and the femoral stem is made of metal, the sleeve will lock the head and the stem . . . .

Assuming, *arguendo*, that the Examiner's statement is correct, Claims 8 and 21 each call for a male junction element, a female junction element, and a sleeve meeting the limitations of amended independent Claims 8 and 21. Specifically, Averill '500 fails to disclose a male portion

*and a female portion being directly engageable in self-locking tapered relationship* to couple the components together and a hollow resilient sleeve having an outer portion engageable with the same female portion and an inner portion engageable with the same male portion while the outer portion of the sleeve engages the female portion and the inner portion of sleeve engages the male portion. In contrast to amended independent Claims 8 and 21, the Examiner has identified two different female junction elements, one of which is capable of direct engagement in self-locking taper relationship and another of which utilizes a hollow sleeve. However, the Examiner has failed to identify disclosure providing a single female junction element meeting the limitation of amended independent Claims 8 and 21.

For the foregoing reasons, Applicants respectfully submit that amended independent Claims 8 and 21, as well as Claims 9, 10, 13, 14, 16, and 23 which depend therefrom, are not anticipated by Averill '500.

#### **Claim Rejection - 35 U.S.C. §103(a)**

Claims 9, 11, and 24 are rejected under 35 U.S.C. §103(a) as being obvious over Bunz '866 in view of U.S. Pat. No. 6,682,566 to Draenert ("Draenert '566"). In forming this rejection, the Examiner relied on Bunz '866 for disclosing all the elements of amended independent Claims 8 and 24, from which Claims 9, 11, and 24 depend. For the reasons set forth above, Bunz '866 fails to disclose or suggest each and every limitation of amended independent Claims 1 and 8. Thus, the Examiner's additional citation of Draenert '566 fails to overcome the deficiencies of Bunz '866, as neither Bunz '866 nor Draenert '566, either alone or in combination, disclose or suggest a sleeve and a modular orthopedic implant according to either of amended independent Claims 1 and 8. Therefore, Applicants respectfully submit that Claims 9, 11, and 24, which depend from amended independent Claims 1 and 8, are not obvious over Bunz '866 in view of Draenert '566.

Claim 12 is rejected under 35 U.S.C. §103(a) as being obvious over Bunz '866 in view of U.S. Patent Application No. 2002/0116068 to McLean ("McLean '068"). In forming this rejection, the Examiner relies on Bunz '866 for disclosing all the limitations of amended independent Claim 8, from which Claim 12 depends. For the reasons set forth above, Bunz '866 fails to disclose or suggest each and every limitation of amended independent Claim 8. The Examiner's additional citation of McLean '068 does not overcome this deficiency as McLean '068

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fails to disclose or suggest a sleeve and modular orthopedic implant meeting the limitations of amended independent Claim 8. Thus, for the foregoing reasons, Applicants respectfully submit that Claim 12, which depends from amended independent Claim 8, is not obvious over Bunz '866 in view of McLean '068.

Claim 24 is rejected under 35 U.S.C. §103(a) as being obvious over Pfaff '560 in view of U.S. Pat. No. 5,108,452 to Fallin ("Fallin '452"). In forming this rejection, the Examiner relies on Pfaff '560 as disclosing all the limitations of amended independent Claim 1. For the reasons set forth above, Pfaff '560 fails to disclose or suggest each and every limitation of amended independent Claim 1. Thus, the Examiner's additional citation of Fallin '452 fails to overcome the deficiencies of Pfaff '560, as neither Pfaff '560 nor Fallin '452, either alone or in combination, disclose or suggest a sleeve and a modular orthopedic implant according to amended independent Claim 1. Thus, for the reasons set forth above, Applicants respectfully submit that Claim 24, which depends from amended independent Claim 1, is not obvious over Pfaff '560 in view Fallin '452.

Claim 24 is rejected under 35 U.S.C. §103(a) as being obvious over Averill '500 in view of Fallin '452. In forming this rejection, the Examiner relies on Averill '500 as disclosing all the limitations of amended independent Claim 1. For the reasons set forth above, Averill '500 fails to disclose or suggest each and every limitation of amended independent Claim 1. Thus, the Examiner's additional citation of Fallin '452 fails to overcome the deficiencies of Averill '500, as neither Averill '500 nor Fallin '452, either alone or in combination, disclose or suggest a sleeve and a modular orthopedic implant according to amended independent Claim 1. Thus, for the reasons set forth above, Applicants respectfully submit that Claim 24, which depends from amended independent Claim 1, is not obvious over Averill '500 in view Fallin '452.

It is believed that the above represents a complete response to the Official Action and reconsideration is requested. Specifically, Applicants respectfully submit that the application is in condition for allowance and respectfully requests allowance thereof.

In the event Applicants have overlooked the need for an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby petition therefor and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

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Should the Examiner have any further questions regarding any of the foregoing, she is respectfully invited to telephone the undersigned at 260-424-8000.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: May 14, 2007

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Name of Registered Representative



Signature

May 14, 2007

Date